

REMARKS

Claim 69 as filed on March 2, 2005 has been amended herein. Claims 70-81 were previously presented. Claims 1-68 were previously canceled. Accordingly, claims 69-81 will be pending upon entry of this amendment.

In the May 19, 2005 Office communication, the Examiner extended the courtesy of notifying applicants that the amendment as filed on February 4, 2005 [*sic*, March 2, 2005] is considered to be non-compliant because a complete listing of the claims was not presented. This notification is gratefully acknowledged. In the March 2, 2005 listing of the claims, applicants inadvertently omitted to list status of all of the canceled claims, i.e. claims 1-68. This amendment corrects that omission, and makes an additional amendment to claim 69.

Amended claim 69 now refers to and defines the recited antigen by its binding to CD40-Ig instead of MR1 as feature (i), in addition to recited features (ii) and (iii). As is the case for MR1 binding, the feature of CD40-Ig binding provides a fully-characterized antigen which adequately defines the anti-gp39 antibody genus of step (b). This result is in accord with the recent case law of the Federal Circuit for defining a genus of antibodies, and in accord with the Synopsis of Application of Written Description Guidelines relied upon by that court. *Noelle v. Lederman*, 355 F.3d 1343, 1349-50 (Fed. Cir. 2004).

This contention is particularly true where, as here, the antigen *itself* was well known in the art at the time of invention, including the structure of its primary amino acid sequence. *See e.g.*, Hollenbaugh et al., 1992, "The human T cell antigen gp39, a member of the TNF gene family, is a ligand for the CD40 receptor: expression of a soluble form of gp39 with B cell co-stimulatory activity," The EMBO Journal 11, 4313-4321 (reference CCR of record; cited *inter alia* at page 2, lines 30 and 36, and at page 7, line 8 of the specification). Moreover, the antibody genus *per se* of step (b) is *not* being claimed. Rather, the claims are directed to *methods* for reducing T cell responsiveness.

In summary, "allowable" claim 67 of the December 3, 2004 Office action was directed to a method of reducing T cell responsiveness *in vivo* to an autoantigen expressing cell, which method

comprises administering to a subject in need of such treatment: (a) an antigen-presenting cell that presents an autoantigen; and (b) an anti-gp39 antibody, wherein the anti-gp39 antibody is MR1 produced by the hybridoma having ATCC Accession No. HB 11048 and is administered prior to, concurrent with, or subsequent to administration of the antigen-presenting cell in an amount effective to reduce T cell responsiveness to the antigen-presenting cell.

Claim 69 as amended herein is directed to a method for reducing T cell responsiveness *in vivo* to an autoantigen expressing cell, which method comprises administering to a subject in need of such treatment: (a) an antigen-presenting cell that presents an autoantigen; and (b) an anti-gp39 antibody which binds to an antigen, which antigen: (i) is bound by a CD40-immunoglobulin (CD40-Ig) fusion protein; (ii) is present on activated but not resting T-cells; and (iii) has the same molecular weight as a protein precipitated by the CD40-Ig fusion protein, wherein the anti-gp39 antibody is administered prior to, concurrent with, or subsequent to administration of the antigen-presenting cell in an amount effective to reduce T cell responsiveness to the antigen-presenting cell.

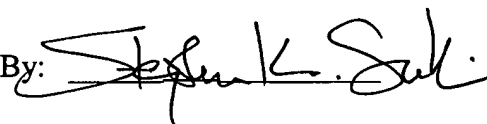
Support for new claims 69-81 is of record in the amendment filed on March 2, 2005. Support for the present amendment to claim 69 is found throughout the specification as filed, for example, in Figures 9-11, at page 6, line 35, page 9, lines 16-19, and especially at page 27, lines 20-21. No new matter has been added.

CONCLUSION

In view of the foregoing amendment and remarks, all claims in this application are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If any issue remains in connection herewith, the Examiner is respectfully invited to call the undersigned to discuss same.

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Respectfully submitted,

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